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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC  
FOURTH FLOOR  
1755 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/903,771

Applicant(s)

MOECKEL ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 20-36 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 13, 15 and 38 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 10-12, 14, 16-19 and 37 is/are rejected.
- 7) ☒ Claim(s) 4 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a written restriction requirement (Paper No. 7, mailed on September 19, 2002), Applicants filed an election received on October 16, 2002 (Paper No. 8). Claims 1-39 are pending in the instant Office action.

### *Election*

2. Applicant's election with traverse of Group I, Claims 1-19, and 37-38, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that Group V directly depends from Group I and, thus, is not separable. This is not found persuasive because, as previously noted, Group V is appropriately considered a method of using the invention of Group I that is an independent invention for the reasons cited previously, particularly because the product can be used in a materially distinct process, such as in the recombinant production of enzyme. The recombinant production of the encoded enzyme is a specific example; Applicants argue that no examples were offered. The dependency of the claims is irrelevant. The traversal is also on the grounds that no search burden exists to examine all the Groups together. As noted previously, each Group is categorized in a distinct class/subclass, wherein the search of more than one class/subclass constitutes a search burden on the Examiner. Applicants request for rejoinder of process claims with allowable products is noted.

The requirement is still deemed proper and is therefore made FINAL. Claims 20-36 and 39 are withdrawn from consideration as non-elected inventions. Claims 1-19 and 37-38 are elected and will be examined herein.

***Priority***

3. The instant application is granted the benefit of priority for the foreign application 10039043.9 filed in Germany on August 10, 2000 as requested in the declaration. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Said papers are in German and would require translation to overcome any intervening art rejection such as the rejections under 35 U.S.C. § 102(a) that follow.

***Information Disclosure Statement***

4. The information disclosure statements filed on October 19, 2001 and March 29, 2002 (Paper Nos. 5 and 6) have been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copy. The Examiner has made several corrections to the citation; no action is required by Applicants.

***Declaration***

5. The Examiner notes that the declaration filed on October 5, 2001 (Paper No. 4) has a typographical error noting that the specification was "attached hereto" when, in fact, the specification was previously filed on July 31, 2001. Because the inventors and the title are correct, the declaration filed after the original filing date (Paper No. 4) is adequate. No action is required by Applicants.

***Objections to the Specification***

6. The specification is objected to for containing a sequence in the sequence listing that is not mentioned in the specification, that is SEQ ID NO:3. The sequence listing originally filed

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contains five sequences. SEQ ID NOs: 1, 2, 4, and 5 are all described in the specification. It is unclear why SEQ ID NO:3 is in the listing if it is not described in the specification.

7. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the source species, *Corynebacterium glutamicum* for completeness.

#### ***Claim Objections***

8. Claims 2 and 4-11 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 9 contain a functional limitation of an exact sequence since both Claims 1 and 3 encode SEQ ID NO:2; the function is an inherent feature of the exact structure. Claim 4 attempts to wholly alter the scope from a coding sequence of SEQ ID NO:1 to a non-coding sequence. Claims 5-8 attempt to broaden the scope to encode more than just an exact sequence. Claim 10 also attempts to broaden the scope, by virtue of its comprising language, to any structure having at least 15 consecutive nucleotides. Claim 11, as depending from Claim 10, has the same problem; however, if Claim 11 depended from Claim 3 it would be an appropriately further limiting claim. Claims 1-11 will be examined as if they were each independent claims so that the broadest reasonable interpretation can be examined herein. Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The washing conditions for stringent hybridization are unclear without a time of the wash. The timing is crucial to define the stringency of the hybridization. Clarification is required.

10. Claims 16-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "*Coryneform*" is a generic name for all bacteria belonging to the genus *Corynebacterium* (a.k.a. *Brevibacterium*); it should be neither italicized nor capitalized as found in Claims 16-17. In Claims 18-19, the term should be replaced by --*Corynebacterium*--.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 5-8 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Claims 5-8 are drawn to polynucleotides having 70-90% identity with SEQ ID NO:1 or being related by hybridization conditions. In both cases, no exact sequences are claimed.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses polynucleotides encoding polypeptides with at least 70% sequence identity to SEQ ID NO:1. Applicants have fully described the genus relating to said SEQ ID NO with both sequence identity limitations and functional limitations (i.e., having LuxR transcriptional activation activity). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 8 and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schmitt (– see IDS). The instant claims are drawn to polynucleotides that comprise at least 15 consecutive nucleotides of SEQ ID NO:1.

Schmitt teaches a *C. diphtheriae* sequence (2021 bp DNA) of histidine kinase that comprises a 22-mer fragment of SEQ ID NO:1 (see attached alignment). This sequence will hybridize to SEQ ID NO:1 by virtue of the hybridization conditions in Claim 8 that are unclear as noted above.

13. Claims 1, 2, 5-8, 10-12, 14, 16, 19, and 37 are rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00842 – see IDS). The instant claims are drawn to polynucleotides that encode SEQ ID NO:2, vectors, and host cells, and methods of making the LuxR protein in said host cells.

Pompejus *et al.* teach a 759 bp DNA sequence, Sequence 297, that exactly encodes SEQ ID NO:2 (see attached alignment). Pompejus *et al.* also teach expression vectors and host cells for the production of the encoded proteins (see Abstract).



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14. Claims 1, 2, 5-8, 10-12, 14, 16, 19, and 37 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790 – see IDS). The instant claims are drawn to polynucleotides that encode SEQ ID NO:2, vectors, and host cells, and methods of making the LuxR protein in said host cells.

Nakagawa *et al.* teach a 636 bp DNA sequence, Sequence 3236, that exactly encodes SEQ ID NO:2 (see attached alignment). Nakagawa *et al.* also teach expression vectors and host cells for the production of the encoded proteins (see Abstract).

#### ***Allowable Subject Matter***

15. The full-length SEQ ID NO:1, which encompasses coding and non-coding portions in and around the nucleotide sequence of LuxR in *C. glutamicum*, is free of the prior art. Only coding fragments, such as encoding SEQ ID NO:2 or exactly SEQ ID NO:3, are disclosed in the prior art.

#### ***Conclusion***

16. Claims 3, 13, 15, and 38 are allowed in the Office action; Claims 4 and 9 are objected to. Claims 1, 2, 5-8, 10-12, 14, 16-19, and 37 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

December 23, 2002

A handwritten signature in cursive script, appearing to read "Kathia Ken", is written over the typed name "KMK".